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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,552	03/02/2004	Paul DiCarlo	01194-461001	3274

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EXAMINER	
PRYOR, ALTON NATHANIEL	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
02/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/791,552	DICARLO ET AL.	
	Examiner	Art Unit	
	ALTON N. PRYOR	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-50 and 52-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-50,52-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 11/14/08 have been fully considered but they are not persuasive. See Applicant's arguments, see paper, filed 11/14/08, with respect to the rejection(s) of claim(s) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this rifle, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37,40-50,52,54-57,66-69,71-84,93-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Smith patent (US 5,888,930).

Smith teaches a spherical bead comprising a polymer having diameter from 5 microns to 5000 microns (col. 2, lines 46-66). Smith states that the polymers "useful for preparation of the beads" include polyvinyl acetate and cellulose acetate (col. 2, lines 57- 66). Polyvinyl alcohol is a hydrolyzed product of polyvinyl acetate. If polyvinyl acetate is used as the starting material for the preparation of the beads as taught by Smith, the resulting bead would actually be polyvinyl alcohol. Therefore, Smith's teaching encompasses polyvinyl alcohol beads. The pore sizes are tiny near the surface and large pores are in the interior (col. 2, lines 50-53). This leads to different pore density between the interior region and the surface region. Larger pores in the interior

region would mean that average pore size at the interior region would be greater than average pore size at the surface region. The bead particles are mixed with a carrier fluid (a mixture of sticker, surfactant and water). See examples 20-22. Smith does not teach the weight ratio of the polymer in the interior region being less than the weight ratio of the polymer at the surface region. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of polymer to include in the interior and on the surface of the particle. One would have been motivated to this in order to develop a particle that would be deliverable through a catheter.

Claims 37-50,52-99 are rejected under 35 U.S.C. 103(a) as being obvious over Mangin (WO 01/66016).

Mangin teaches an embolic particle comprising a polymer selected from polyvinyl alcohol (PVA), polylactic acid, alginate (polysaccharide), etc (page 4, lines 5-7 and 29-30, page 5 lines 9-30). The size of the particle ranges from 355 to 500 microns (page 7, lines 18-22). The particle contains voids on the surface and in the interior region where large voids are in the interior region (figure IB). Because large voids are in the interior portion, the density of the surface area must be larger than that of the interior portion. Due to the larger void concentration, the interior region would have a larger average pore size than the surface of the particle. Note, the process of manufacturing the particle involves oil-in-water emulsification plus the incubation of the emulsification to leech out the soluble material (page 8, lines 17~25). This inherently results in larger pores generated in the interior region than in the surface region. The particle has a

sphere shape (page 7, lines 15-17); therefore it is inherent that the particle would have a sphericity of at least 0.9.The particle comprises mostly PVA or other polymer and has a volume porosity of 20-50% or 50- 90% (page 8, lines 9). Therefore, the particle would be expected to have the density within the claimed range. Mangin teaches that the composition can comprise the embolic particle in a carrier such as a surfactant, saline and contrast agent (page 5 lines 5-12, page 12 lines 11-13, page 14 line 32 – page 15 line 2). Smith does not teach the weight ratio of the polymer in the interior region being less than the weight ratio of the polymer at the surface region. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of polymer to include in the interior and on the surface of the particle. One would have been motivated to this in order to develop a particle that would be deliverable through a catheter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-50.52-57,67,71,72,74-84,95,96,99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 7449236. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '236 makes claim to a composition comprising a plurality of spherically shaped particles comprising polyvinyl alcohol or polysaccharide and having a diameter of about 500 microns or less, wherein some of the particles having a diameter of about 500 microns or less have a first density of pores and a first average pore size in an interior portion and a second average pore size in the surface portion, the first density is different from the second density and the first average pore size is larger .than the second average pore size and the particles being in a carrier fluid such as saline or contrast agent. USPN '236 make claim to the particle being coated with bioabsorbable material. USPN '236 does not make claim to the composition comprising surfactant, concentration of the particles in the polymer, halogenated polymer and the molecular of the polymer. It would have been obvious to employ a surfactant since Examples 1,5,7,12,16,20 and 21 of USPN '236 specification it is taught that surfactants are part of the particle composition. It would have been obvious to one having ordinary skill in the art to optimize the polymer concentration and the polymer molecular weight. One would have been motivated to this in order to develop an embolic particle that would be deliverable through a catheter.

Claims 37,4043-50.52-57,66-70,73-84,9394,95,97-99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12,14 of U.S. Patent No. 7462366. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '366 makes claim to a composition comprising a plurality of spherically shaped particles (optionally coated) comprising polyvinyl alcohol having a first region including pores having a first predominant pore size and containing a therapeutic agent, and a second region surrounding the first region and including pores having a second predominant pore size. USPN '366 defines the particle size as 1200 microns or less (column 4 lines 1-9). USPN '366 does not make claim to the composition comprising carrier fluid, the concentration of the particles in the polymer, halogenated polymer and the molecular of the polymer. It would have been obvious to employ a carrier fluid since at column 5 lines 3-17 the USPN '366 specification it is taught that carrier fluids are part of the particle composition. It would have been obvious to one having ordinary skill in the art to optimize the polymer concentration and the polymer molecular weight. One would have been motivated to this in order to develop a particle that would be deliverable through a catheter.

Claims 37,40,41,43-50,52-59,63,64,68,72-88,90,91,95-99. are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,17,36-41 of U.S. Patent No.7311861. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '861 makes claim to a process of making a composition comprising a plurality of spherically shaped

particles comprising a polymer and having a diameter from about 50 microns to 1000 microns. USPN '861 does not make claim to the composition comprising surfactant, concentration of the particles in the polymer, halogenated polymer and the molecular of the polymer. It would have been obvious to employ a carrier fluid since the specification of USPN '861 ht that carrier fluids are part of the particle composition. It would have been obvious to one having ordinary skill in the art to optimize the polymer concentration and the polymer molecular weight. One would have been motivated to this in order to develop a particle that would be deliverable through a catheter.

The Applicants also have several applications that appear to warrant a provisional obviousness type double patenting rejection. Please file terminal disclaimers over the following applications or defend why terminal disclaimers should not be provided.

Claim 31 in 10/651475

Claims 1 and 3 in 10/700970

Claims 1-3,12,21-23,25,32,33,47 and 54 in 10/215594

Claims 1-3,5,7,11-13,15,19,23 and 30 in 12/235978

If an obviousness type double patenting rejection is made over any of these applications in the next office action the office may be made final.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616